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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,159	06/27/2001	Shigeru Kawahara	206269US0PCT	9776
22850	7590	08/31/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,159	KAWAHARA ET AL.	
	Examiner	Art Unit	
	Paul A. Zucker	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9 and 11-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-15 and 17-23 is/are allowed.
- 6) ☒ Claim(s) 5-9, 16 and 24-29 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 28 June 2004 has been entered.

Current Status

2. This action is responsive to Applicants' amendment of 28 June 2004.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Applicant's cancellation of claims 1-4 and 10 is acknowledged.
5. Applicant's addition of new claims 16-29 is acknowledged.
6. Claims 5-9 and 11-29 are pending.
7. The rejection under 35 USC § 112, second paragraph, set forth in paragraph 4 of the previous Office Action mailed 26 August 2003 is withdrawn in response to Applicants' amendment.

New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

8. Claims 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 recites the limitation "crystallization" in line 9. There is insufficient antecedent basis for this limitation in the claim. Claim 24 and its dependents are therefore rendered indefinite.

Claim Rejections - 35 USC § 102/103

9. Claims 5-9 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Claude et al (US 5,510,508 04-1996).

Claude discloses (Column 4, lines 18-26) a process for the crystallization of N-[N-(3,3-dimethylbutyl)-L-aspartyl]-L-phenylalanine methyl ester (Neotame) from water-methanol solution that contains little or no methanol. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

In the alternative, the invention as a whole is obvious over the disclosure of Claude since it provides no patentable modification of the process as disclosed by Claude: recrystallization of Neotame from a water-methanol solution at a temperature below 40°C.

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Instantly claimed is a method for the crystallization of N-[N-(3,3-dimethylbutyl)-L—aspartyl]-L-phenylalanine methyl ester (Neotame) to obtain crystals having a specified set of characteristic peaks. Claude further discloses (Column 4, line 19) that crystallization is carried out below 40°C.

Claude teaches (Column 4, lines 18-26) a process for the crystallization of N-[N-(3,3-dimethylbutyl)-L—aspartyl]-L-phenylalanine methyl ester (Neotame) from water-methanol solution that contains little or no methanol. Claude is silent with respect to the exact amount of methanol in solution but indicates that methanol is removed by evaporation and thus a low concentration or absence of methanol (cf. instant limitation in claim 7 of “15 wt.% or less” methanol content) can be assumed. Claude further teaches (Column 4, line 19) that crystallization is carried out below 40°C. This is within 10°C of the temperature of 30°C claimed as a lower limit in the instant case (Claim 9). It is therefore reasonable to assume that crystallizations performed at 35°C, for example, under the conditions described by Claude will have the same diffraction characteristics as those claimed in the instant application. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Small adjustments in solvent ratios in the solvent composition disclosed by Claude to achieve the optimum result from the crystallization process would also be well within the skill of one of ordinary skill in the art.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art. The motivation would have been to purify Neotame, a compound used as an artificial sweetener for human consumption. There would have been a reasonable expectation for success since the starting material, solvent composition and product are the same as that taught by Claude.

Examiner's Response to Applicants' Remarks with Regard to This Rejection

10. Applicants have presented several arguments with regard to this rejection. The Examiner responds to these below:

- a. Applicants argue that Claude never states any actual temperature for the crystallization, only that it is kept below 40°C. The Examiner agrees and points out that there is a 10°C overlap between Applicants' claimed 30°C lower limit and Claude's upper limit. Applicants' claimed process therefore reads on Claude's process.
- b. Applicants argue that it is the temperature of a presumed water bath that is being controlled by Claude. The Examiner disagrees that there is any evidence that such is the case. There is no evidence in Claude to support the conclusion that it is the temperature of a water bath that is reported. Especially so, since there is no evidence of a water bath. While the Examiner agrees that such a process might reasonably be conducted using a water bath as posited by Applicants, there is no evidence on the record that such is the case in this instance.

- c. Applicants further argue that the method of Claude does not produce A-type crystals. The Examiner points out that Applicants have demonstrated only that the method of Claude, *as interpreted by Applicants*, does not produce A-type crystals.
- d. Applicants argue that it is obvious to those of ordinary skill in the art that the temperature of the bath and not the crystallization solution itself that is maintained at below 40°C. The Examiner disagrees. There is no evidence of such a bath on the record.
- e. Applicants argue that an oil is produced by Kawahara at above 30°C. The Examiner points out that Applicants accomplish (Specification, page 13, lines 12-15) the nucleation/crystallization of neotame at 40°C without formation of an oil.

Applicant's arguments filed 28 June 2004 have been fully considered but they are not persuasive for the reasons indicated above.

11. The rejection under 35 USC § 103 set forth in paragraph 6 of the previous Office Action mailed 26 August 2003 is withdrawn in response to Applicants' amendment.

Claim Objections

12. Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

13. Claims 12-15 and 17-23 are allowed. Claims 24-29 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: Claude's process is limited to temperatures of crystallization below 40°C. The instantly claimed processes that are limited to temperatures of 40°C or above are therefore patentable over Claude. In addition, since the crystallization of Claude proceeds without difficulty and there is no realization within Claude that different polymorphic forms exist, one of ordinary skill in the art would not have been motivated to seed the crystallization solution. The instantly claimed processes employing seed crystals are also, therefore, patentable over the teachings of Claude.

Conclusion

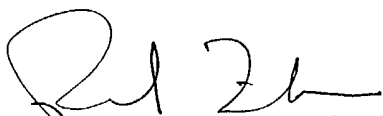
14. Claims 5-9 and 11-29 are pending. Claims 5-9, 16 and 24-29 are rejected. Claim 11 is objected to. Claims 12-15 and 17-23 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Paul Zucker', is written over a horizontal line.

Paul A. Zucker, Ph. D.
Patent Examiner
Technology Center 1600